

JAN - 7 2011

## Special 510(k) Summary

K103152

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

### 807.92(a)(1)

#### Submitter Information

Esaote S.p.A.  
Via Siffredi 58  
Genoa, Italy 16153

Contact Person: Allison Scott  
317.569.9500 x106  
ascott@ansongroup.com

Date: October 22, 2010

### 807.92(a)(2)

Trade Name: 6250 System

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse Doppler imaging system 892.1550  
Ultrasonic pulsed echo imaging system 892.1560

Classification Number: 90IYN; 90IYO; 90ITX

### 807.92(a)(3)

#### Predicate Device(s)

K051308, K052805,  
K060827, K081386 and  
K091009

6150

Esaote, S.p.A.

807.92 (a)(4)

### **Device Description**

The 6150 is a mainframe ultrasound system, used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping, Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). The system is equipped with a LCD Color Display, a control panel and is capable of operating Linear, Convex, and Phased array probes.

The 6150 system has been cleared by FDA via K051308, K052805, K060827, K081386 and K091009.

The modified 6150, with respect to the cleared version 6150 via K051308, K052805, K060827, K081386 and K091009, is due to the improvements of the system. These modifications, that do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

- a. New keyboard (control panel), where some control keys (knobs and keys) have been replaced by a touch screen.
- b. New plastic housing of the system both to include the touch screen and to give a new style
- c. New keyboard group PCBs lay out to interface the touch screen and to match the new organization of the panel keys.
- d. Software/Firmware modification to translate the touch screen information for the software: main software characteristics and performances have not been changed.

The 6250 is the model name of the modified 6150. The set of probes of the 6150 and the 6250 is exactly the same.

The 6250 system is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

### **Intended Use(s)**

Esaote's Model 6250 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6250 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

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The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always be seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

807.92(a)(6)

**Technological Characteristics**

The modifications reflected in this Special 510(k) for the 6250 are intended to improve the system's performance. The modifications have not altered the fundamental scientific technology or the intended use of the unmodified version of the 6150 cleared via K051308, K052805, K060827, K081386 and K091009.



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Esaote S.p.A.  
% Ms. Allison Scott, RAC  
Regulatory Associate  
Anson Group  
11460 N. Meridian Street, Suite 150  
CARMEL IN 46032

JAN - 7 2011

Re: K103152

Trade/Device Name: 6250 Ultrasound Systems  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: October 22, 2010  
Received: October 26, 2010

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 6250 Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

<u>PA230</u>	<u>LA532</u>	<u>CA631</u>	<u>TEE022</u>
<u>PA122</u>	<u>LA932</u>	<u>2CW</u>	<u>TEE022</u>
<u>PA023</u>	<u>C5-2R13</u>	<u>5CW</u>	<u>IOE323</u>
<u>PA240</u>	<u>CA123</u>	<u>HF CW</u>	<u>LP323</u>
<u>LA332</u>	<u>CA421</u>	<u>EC123</u>	<u>BC431</u>
<u>LA435</u>	<u>CA621</u>	<u>EC1123</u>	<u>BL433</u>
<u>LA522</u>	<u>CA430</u>	<u>EC1123</u>	
<u>LA523</u>	<u>CA431</u>	<u>BE1123</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

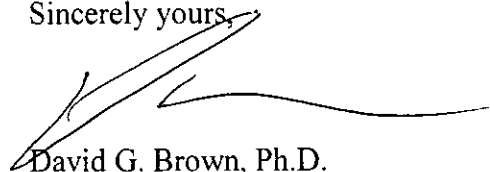
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,



David G. Brown, Ph.D.  
Acting Director  
Division of Radiological Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure(s)

Model 6250

JAN - 7 2011

Indications for Use

K103152

510(k) Number (if known):

Device Name: 6250 Ultrasound Systems

Esaote's Model 6250 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6250 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

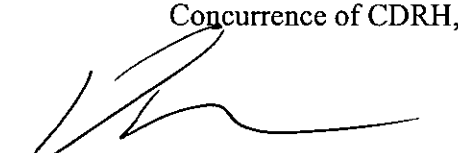
The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always be seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K103152

# 6250 (Modified 6150)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (VIM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13
Abdominal	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13
Intracranial (Abdominal)	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13
Intracranial Neurological	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13
Pediatric	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13
Small Organ [1]	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13, 14
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12
Adult Cephalic	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12
Cardiac [2]	P	P	P	P	P	P	P	P	P (1b)	5, 6, 7, 8, 10, 11, 12
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 10, 11, 12
Transesophageal (Non Cardiac)										
Transrectal	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13, 14
Transvaginal	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13
Laparoscopic	P	P	P	P	P	P	P	P	P	P
Musculo-skeletal Conventional [3]	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13, 14
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13, 14
Other (Urological)	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 12, 13

N: New indication; P: Previously cleared by FDA; Excluded under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo-Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compass M-Mode (CM-M)

[6] 3D

[7] 4D

[8] Vpan

[9] X-view

[10] Stress

[11] Xstrain


[12] Compound Imaging (M-view)

[13] Trapezoidal View (TP-View)

[14] Elastography

[15] Includes contrast (Cntrl) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via K051308, K052805, K060827, K081385 and K091009

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K 16103152

# PA230

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application		Mode of Operations									Other (specify)
		B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	
Ophthalmic											
Fetal		P	P	P	P	P	P	P		P	5, 6, 9
Abdominal		P	P	P	P	P	P	P	P	P	5, 6, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P	P		P	5, 6, 9
Small Organ [1]		P	P	P	P	P	P	P		P	5, 6, 9
Neonatal Cephalic											
Adult Cephalic		P	P	P	P	P	P	P	P	P	5, 6, 9
Cardiac [2]		P	P	P	P	P	P	P	P	P (16)	5, 6, 9, 10, 11
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		P	P	P	P	P	P	P	P	P	5, 6, 9
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D

[9] XView


[10] Stress

[11] Xstrain

[16] Includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via K100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

  
Division Sign-Off  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152



# PA122

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (VVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal											
Abdominal	P	P	P	P	P	P	P		P		5, 6, 9
Intraoperative (Abdominal)											
Intraoperative Neurological	P	P	P	P	P	P	P		P		5, 6, 9
Pediatric											
Small Organ [1]											
Neonatal Cephalic	P	P	P	P	P	P	P		P		5, 6, 9
Adult Cephalic											
Cardiac [2]	P	P	P	P	P	P	P	P	P		5, 6, 9, 10, 11
Transesophageal [Cardiac]											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P		5, 6, 9
Laparoscopic											
Musculo-skeletal Conventional											
[3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes  
Breast, Thyroid and Testicles

[2] Cardiac is Adult and  
Pediatric

[3] Musculo Skeletal - Nerve  
Block

[4] Combined modes are:  
B+M+PW+CW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D

[9] XView

[10] Stress

[11] Xstrain

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics



(Division Sign-Off)

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 5103152

**PA023**

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Modes of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (V/M)	Hemodynamic Imaging (HEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	5, 6, 9
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	5, 6, 9
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P		P	5, 6, 9, 10, 11
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	5, 6, 9
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B-M, PW-CW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D

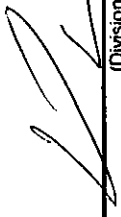
[9] XView

[10] Stress

[11] Xstrain

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K 16163152

# PA240

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operation									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (HEI)	Other (specify)
Ophthalmic										
Petal	P	P	P	P	P	P	P			5, 6, 9
Abdominal	P	P	P	P	P	P	P			5, 6, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P			5, 6, 9
Small Organ [1]	P	P	P	P	P	P	P			5, 6, 9
Neonatal Cephalic	P	P	P	P	P	P	P			5, 6, 9
Adult Cephalic	P	P	P	P	P	P	P			5, 6, 9
Cardiac [2]	P	P	P	P	P	P	P	P	1 (14)	5, 6, 9, 10, 11
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transarterial										
Transvenous										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P			5, 6, 9
Endoscopic										
Musculo-skeletal Conventional										
[3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs include Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo-Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compass M-Mode (CM-M)

[6] 3D

[7] XView


[8] Stress

[9] Xstrain

[10] Includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152

# LA332

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Mode of Operations										
Clinical Application	B	M	FWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	6, 8, 9, 10, 12, 12, 13
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Other (Urological)	P	P	P		P	P	P		P	6, 8, 9, 12, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac: is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] Vpan

[9] XView

[10] Stress

[11] Strain


[12] Compound Imaging (Mview)

[13] Trapezoidal View (TP-View )

[14] Elastography

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K k103152

# LA435

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (VFM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Other (Urological)	P	P	P		P	P	P		P	6, 8, 9, 12, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+TI)

[6] 3D

[8] Vpan

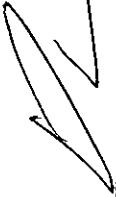
[9] XView

[12] Compound Imaging (Mview)

[13] Trapezoidal View (TP-View )

[14] Elastography

Previously cleared via k100931

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K k103152

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro

# LA522

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	6, 8, 9, 12, 13, 14
Other (Urological)	P	P	P		P	P	P		P	6, 8, 9, 12, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

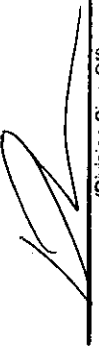
[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

[13] Trapezoidal View (TP-View)

[14] Elastography

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

# LA523

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Petal	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P	P	P	6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P	P	P	6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	6, 8, 9, 10, 12, 13
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P	P	P	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P	P	P	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	P	P	P		P	P	P	P	P	6, 8, 9, 12, 13, 14
Other (Unlabeled)	P	P	P		P	P	P		P	6, 8, 9, 12, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] 3D

[6] Vpan

[7] XView


[10] Stress

[11] Strain

[12] Compound Imaging (Mview)

[13] Trapezoidal View (TP-View)

[14] Elastography

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K h103152

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

# LA532

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P	P	P		6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P	P	P		6, 8, 9, 12, 13
Neonatal Cephalic	P	P	P		P	P	P	P	P		6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P	P	P		6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12, 13

N: New Indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD


[6] 3D

[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

[13] Trapezoidal View (TP-View)

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K h103152

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics



# LA923

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+TD

[6] 3D

[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

[13] Trapezoidal View (TP-View)

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510K K103152

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Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro

# C5-2R13

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (Specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Other (Urological)	P	P	P		P	P	P		P	5, 6, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D

[8] Vpan


[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (Mview)

Previously cleared via k100931

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K k103152

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

# CA123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	R	M	PWD	CWD	Color Doppler	Amplitude Doppler (PT)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Neonatal Cephalic	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

[5] M+PW+CFM+TD

[6] 3D

[8] Vpan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (Mview)

Previously cleared via k100931



(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103152

Prescription Use Only Per 21 CFR 801 Part D  
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# CA421

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Other (Urological)	P	P	P		P	P	P		P	5, 6, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

- [1] Small Organs includes  
Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve  
Block
- [4] Combined modes are:  
B+M+PW+CFM+PD
- [5] Compass M-Mode (CMM)  
[6] 3D
- [8] Vpan
- [9] XView
- [12] Compound Imaging (Mview)

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

# CA621

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	IWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (Specify)
Ophthalmic										
Fetal	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD


[5] Compass M-Mode (CMM)

[6] 3D

[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152

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Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro

# CA430

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P [16]	5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional	P	P	P		P	P	P		P	5, 6, 8, 9, 12
[3]										
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Other (Urological)	P	P	P		P	P	P		P	5, 6, 8, 9, 12


N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve Block
- [4] Combined modes are: B+M+PW+CFM+PD
- [5] Compass M-Mode (CMM)
- [6] 3D
- [8] Vpan
- [9] XView
- [10] Stress
- [11] Xstrain
- [12] Compound Imaging (Mview)

[16] Includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

  
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510K k103152

# CA431

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Modes of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P (16)	5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Other (Urological)	P	P	P		P	P	P		P	5, 6, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D

[8] Vpan

[9] XView

[10] Stress


[11] Xstrain

[12] Compound Imaging (Mview)

[16] Includes contrast (CEI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
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510K K103152

# CA631

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined (4)	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Other (Urological)	P	P	P		P	P	P		P		5, 6, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D

[8] Vpan


[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (Mview)

Previously cleared via #100931

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics



2CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E


[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

Previously cleared via k100931

  
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 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K k103152

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 Concurrence of CDRH, Office of In Vitro Diagnostics

5CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:



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# HF CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (fD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										


N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

# EC123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P	P		5, 6, 8, 9, 12
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Transvaginal	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P	P	P	5, 6, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD


[5] Compass M-Mode (CMM)

[6] 3D

[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

# EC1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (FD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P	P	P		5, 6, 8, 9, 12
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P	P	P		5, 6, 8, 9, 12, 14
Transvaginal	P	P	P		P	P	P	P	P		5, 6, 8, 9, 12
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P		P	P	P	P	P		5, 6, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D


[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

[14] Elastography

Previously cleared via k100931

  
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510K K103152

Prescription Use Only Per 21 CFR 801 Part D  
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# EC1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)
	B	M	IWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined (4)	Harmonic Imaging (TEI)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transcranial	P	P	P		P	P	P	P	P		5, 6, 8, 9, 12, 13, 14
Transvaginal	P	P	P		P	P	P	P	P		5, 6, 8, 9, 12, 13, 14
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P		P	P	P	P	P		5, 6, 8, 9, 12, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D

[8] Vpan


[9] XView

[12] Compound Imaging (Mview)

[13] Trapezoidal view (TPView)

[14] Elastography

Previously cleared via k100931

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K k103152

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro

# BE1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined (4)	Color Velocity Mapping (VVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P	P	P	5, 6, 7, 8, 9, 12
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P	P	P	5, 6, 7, 8, 9, 12
Transvaginal	P	P	P		P	P	P	P	P	5, 6, 7, 8, 9, 12
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
[3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P	P	P	5, 6, 7, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D


[7] 4D

[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

Previously cleared via k100931

  
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# TEE022

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application		Mode of Operations										Other (specify)
		B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic												
Fetal												
Abdominal												
Intraoperative [Abdominal]												
Intraoperative Neurological												
Pediatric												
Small Organ [1]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac [2]												
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P		5, 6, 9, 10, 11	
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Conventional												
[3]												
Musculo-skeletal Superficial [3]												
Other (Urological)												

N: New Indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B-M+PW+CFM+PD


[5] Compass M-Mode (CMM)

[6] 3D

[9] XView

[10] Stress

[11] Xstrain

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K K103152

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
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# TEE022

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined (H)	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	5, 6, 9, 10, 11
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D


[9] XView

[10] Stress

[11] Xstrain

Previously cleared via k100931

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510K k103152


# IOE323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (Specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Intraoperative (Abdominal)	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve Block
- [4] Combined modes are: B+M+PW+CFM+PD
- [6] 3D
- [8] Vpan
- [9] XView
- [12] Compound Imaging (Mview)
- [13] Trapezoidal View (TF-View)
- [14] Elastography

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K 2103152

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

# LP323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined (H)	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P		P	6, 8, 9, 12, 13	
Abdominal	P	P	P		P	P	P		P	6, 8, 9, 12, 13	
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P	6, 8, 9, 12, 13	
Small Organ [1]	P	P	P		P	P	P		P	6, 8, 9, 12, 13	
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P	6, 8, 9, 12, 13	
Laparoscopic	P	P	P		P	P	P		P	6, 8, 9, 12, 13	
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

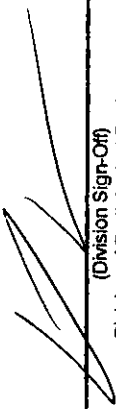
[6] 3D

[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

[13] Trapezoidal View (TP-View)

 (Division Sign-Off)  
 Division of Radiological Devices  
 Office of In Vitro Diagnostic Device Evaluation and Safety  
 510K K103152

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH, Office of In Vitro

# BC431

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PTD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)		
Ophthalmic											
Fetal	P	P	P		P	P	P	P	P		5, 6, 7, 8, 9, 12
Abdominal	P	P	P		P	P	P	P	P		5, 6, 7, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P	P	P		5, 6, 7, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P	P	P		5, 6, 7, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		5, 6, 7, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P	P	P		5, 6, 7, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional	P	P	P		P	P	P		P		5, 6, 7, 8, 9, 12
[3]											
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		5, 6, 7, 8, 9, 12
Other (Urological)	P	P	P		P	P	P		P		5, 6, 7, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B-M+PW+CFM+PD

[5] Compass M-Mode (CMM)

[6] 3D

[7] 4D

[8] Vpan


[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (Mview)

Previously cleared via k100931

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K 14103152

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics

# BL433

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13
Neonatal Cephalic	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13
[3]										
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13
Other (Urological)	P	P	P		P	P	P		P	6, 7, 8, 9, 12, 13

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes  
Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve  
Block

[4] Combined modes are:  
B+M+PW+CFM+PD

[6] 3D

[7] 4D


[8] Vpan

[9] XView

[12] Compound Imaging (Mview)

[13] Trapezoidal view (TFView)

Previously cleared via k100931

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K k103152

Prescription Use Only Per 21 CFR 801 Part D  
Concurrence of CDRH, Office of In Vitro Diagnostics